APR 1 5 2002

K020905
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BIOMET
CORPORATE HEADQUARTERS

## Summary of Safety and Effectiveness

**Applicant/Sponsor:** Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

**Contact Person:** Patricia Sandborn Beres
Senior Regulatory Specialist
Phone: (574) 267-6639

**Proprietary Name:** NBX – Non-Bridging External Fixator

**Common Name:** External Fixator

**Classification Name:** Single/Multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

**Legally Marketed Device to which Substantial Equivalence is Claimed:** Biomet External Wrist Plate (K003240)

**Device Description:** The device is an external wrist fixator made of radiolucent polymer, polycarbonate. The fixator is a non-bridging device, which means that it does not cross the wrist. A non-bridging device gives patients the ability to utilize wrist function.

The device consists of two plates with multiple pin holes. Pins are inserted through the plates, into the bone and held in place by the interference of the two plates. The plate has an external bracket that allows pins to be inserted from the side for additional fixation. If desired, distraction of the fracture site may be achieved with adjustment of a threaded pin placed within a slot on the distal end of the plate.

**Intended Use:** Stabilization of open and/or unstable fractures of the distal radius, where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of external fixation.

**Summary of Technologies:** The technological characteristics (materials, design, sizing and indications) of the NBX – Non-Bridging External Fixator are similar to or identical to the predicate device.

**Non-Clinical Testing:** Mechanical testing was conducted to insure the design changes would not effect the safety of the device.

**Clinical Testing:** None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

APR 15 2002

Re: K020905
Trade/Device Name: NBX-Non-Bridging External Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: II
Product Code: LXT
Dated: March 19, 2002
Received: March 20, 2002

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K020905

**Device Name:** NBX – Non-Bridging External Fixator

**Indications For Use:**
Stabilization of open and/or unstable fractures of the distal radius, where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of external fixation.

for Mark N Milkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020905

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)